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09/881,097	06/15/2001	Valerie De La Poterie	05725.0905-00	7312
22852	7590	09/07/2007	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			LAMM, MARINA	
			ART UNIT	PAPER NUMBER
			1617	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/881,097  
Filing Date: June 15, 2001  
Appellant(s): DE LA POTERIE ET AL.

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Debarshi Rahul Das  
For Appellant

**EXAMINER'S ANSWER**

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This is in response to the appeal brief filed 11/20/06 appealing from the Office action mailed 10/20/05.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

No amendment after final has been filed.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is incomplete. The changes are as follows: Applicants request reversal of the 35 U.S.C. 112, first paragraph rejection of Claims 1-10, 12, 13, 15-18, 21-56 and 59 as applicable to the non-elected species.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 12, 13, 15-18, 20-56 and 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite the limitation "at least one thermal transition agent chosen from semi-crystalline compounds, which undergoes a change of state at a transition temperature,  $T_t$ , chosen within a temperature range from 25° C to 80° C, the at least

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one thermal transition agent being not water-soluble in water maintained at a temperature below the transition temperature,  $T_t$ ". The instant specification on p. 7 discloses that thermal transition agents may be semi-crystalline polymers such as polycaprolactones. There are semi-crystalline polymers that would be encompassed by the claim, that are not described in the specification. The instant claims recite a genus of semi-crystalline compounds that are defined only by their transition temperature and lack of water solubility at a temperature below the transition temperature. To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed compound, or any combination thereof. Here, the only factor present is certain physical properties of the compound. There is no identification of any structures or structural elements (e.g. monomers) that this compounds must possess. Thus, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus because one skilled in the art can not structurally visualize any semi-crystalline thermal transition agents, except for the single disclosed polycaprolactones; thereby, not reasonably meeting the written description requirements of 35 U.S.C. 112, first paragraph. See MPEP 2163.

### **(10) Response to Argument**

The Applicant argues: "...the Examiner has not set forth express findings to support the written description rejection...Notably, however, and as Appellants have argued in the record, Federal Circuit case law establishes that a single species can provide adequate written description support for a larger genus where the disclosure provides sufficient information and guidance that one skilled in the art would readily know the other members of the genus that could be used. See *e.g., Utter v. Hiraga*, 845 F.2d 993, 998-99, 6 USPQ2d 1709, 1714 (Fed. Cir. 1988)." See p. 13-14 of the Brief. In response, this is not the case here. The instant specification does not provide **sufficient information** and **guidance** for one skilled in the art as to what members of the genus of semi-crystalline compounds having the specified transition temperature and water-solubility, other than polycaprolactones, could be used in the instant invention. Without a correlation between structure and function, the claim does little more than define the claimed invention by function. That is not sufficient to satisfy the written description requirement. See *University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) ("definition by function ... does not suffice to define the genus because it is only an indication of what the genus does, rather than what it is").

Further, the Applicant argues: "In this case, however, it is clear that the other members of the genus would perform similarly by the fact that the genus of thermal transition agents is explicitly defined by (1) the fact that they are semi-crystalline

compounds; (2) a specific transition temperature range; and (3) lack of water solubility below the transition temperature." See pp. 14-15 of the reply. In response, it is not clear what are these "the other members of the genus" referred to by the Applicant. The Applicant was invited to name such compounds (see Office Action dated 10/20/05 at p. 4), but in response asserted that "naming such compounds is unnecessary as the specification clearly sets forth the properties of the claimed thermal transition agents." See p. 16 of the Brief. In *Enzo Biochem, Inc. v. Gen-Probe*, 323 F.3d 956, 63 USPQ2d 1609 (Fed. Cir. 2002), the Court stated that the legal standard for sufficient written description is met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Further, *Enzo* adopted the USPTO's Written Description Guidelines that a functional description is adequate when it is coupled with a disclosed correlation between the function and a structure that is sufficiently known or disclosed. In this case, the Appellant's Specification provides a single example of the thermal transition agent that possesses the claimed properties. No structure/property correlation is disclosed for the members of the claimed genus. Not having other thermal transition agents which have been specifically named or mentioned in a sufficient manner that provides "sufficiently detailed, relevant identifying characteristics ... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics

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when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics" as required by *Enzo*, one is left to select from the myriad of possibilities encompassed by the broad disclosure with insufficient guidelines.

In summary, the Appellants' Specification does not contain a written description sufficient to show they had possession of the full scope of their claimed invention at the time the application was filed, as required by Federal Circuit precedent.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.


For the above reasons, it is believed that the rejections should be sustained.

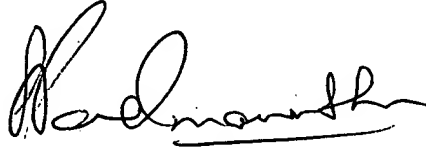
Respectfully submitted,

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